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| 09/926,411 | 10/29/2001 | Ryuji Ueno | 215246US0PCT | 2073 |

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EXAMINER

AZPURU, CARLOS A

ART UNIT PAPER NUMBER

1615

DATE MAILED: 02/26/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/926,411

Applicant(s)
Ueno

Examiner
Carlos Azpuru

Art Unit
1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☒ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 & 5 6) ☐ Other:

Art Unit: 1615

DETAILED ACTION

Receipt is acknowledged of the preliminary amendment filed 10/29/01.

Information disclosure statements were filed on 02/12/02, and 01/02/03.

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 provides for the use of a macrolide, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 7 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Art Unit: 1615

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is indefinite in the use of the phrase "aims at improving tear film breakup time", in that this is merely an intended result which is neither particularly set out, nor satisfactorily quantified. Further, there is no way for the ordinary practitioner to adequately ascertain the improvement in tear drop time without undue experimentation as the amount of improvement is not set out in the claim. Correction is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman.

Peyman disclose the treatment of dry eye with a formulation comprising tacrolimus (FK506), which is a macrolide immunosuppressant via topical administration (see Abstract; col. 2, lines 58-62. Therefore, those of ordinary skill would have expected similar therapeutic results from the use of the instant macrolide compositions in the

Art Unit: 1615

treatment of dry eye. There are no unusual and/or unexpected results which would rebut prima facie obviousness. As such, the composition of a macrolide and the use thereof in the treatment of dry eye would have been obvious given the disclosure of Peyman.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Yang et al.

Yang et al disclose a composition of FK506 (see page 134, second column, FK506 treatment). The intended use of the composition does not lend the instant claims patentable weight over the prior art. The property described in claim 5 as “aims at improving tear film breakup time” is similarly unable to overcome the prior art, since at best, this is an intended property which is neither quantified, nor adequately set out to distinguish over Yang et al. As such , the instant claims are anticipated by Yang et al.

Claims 1, 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsubota et al.

Tsubota et al disclose the use of cyclosporin a (a macrolide) in the treatment of dry eye (see page 124; paragraph “cyclosporin A”). The instant claims are anticipated by Tsubota et al.

Art Unit: 1615

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Iwamoto et al.

Iwamoto et al disclose a composition comprising FK506 (a macrolide) as the active ingredient. The instant claims are anticipated by Iwamoto et al.

Claim 1, 2, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Tiemessen.

Tiemessen disclose a macrolide composition comprising a cyclosporin, a rapamycin or an ascomycin (see Abstract). The instant claims are anticipated by Tiemessen.

Claims 1, 2, 4, and 5 rejected under 35 U.S.C. 102(b) as being anticipated by Hersperger et al.

Hersperger et al disclose a macrolide composition comprising ascomycins. The instant claims are anticipated by Hersperger et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is 703/308-0237. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

Art Unit: 1615

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

**CARLOS A. AZPURU
PRIMARY EXAMINER
GROUP 1500**

ca
February 21, 2003

A handwritten signature in black ink, appearing to read 'Carlos Azpuru', with a large, stylized loop at the end.